Congratulations on being a faculty sponsor! You fulfill a significant role in your students’ research experience at Marywood University. Part of your responsibility is to ensure the protection of human participants in your students’ projects, and the accurate submission of applications for review by one of Marywood University’s research committees. As such, the Office of Research and Sponsored Programs (ORSP) would like to inform you about some of the requirements of our Human Research Protection Program.

**Institutional Policy - Review of Research**

The Policy Committee of Marywood University had last updated its policy concerning *Institutional Review of Research Involving Human Participants* in April of 2011. Research by faculty, staff, or students of Marywood University involving human participants, conducted at Marywood University or under its sponsorship at another location, must comply with applicable policies, procedures and guidelines for the protection of human subjects.

All research that can be defined as "a systematic investigation designed to develop or contribute to generalizable knowledge" (45 CFR 46) must be reviewed and approved by the Institutional Review Board for the Protection of Human Participants (IRB) or submitted as an exemption request for review to the Exempt Review Committee (ERC).

Research activities that are intended only to teach research methods to students may not require IRB/ERC review, as long as certain criteria are met. Research course instructors should obtain *Guidelines for Classroom Projects* online or by contacting the Director of Research Compliance, who assists with any questions regarding classroom research assignments.

IRB/ERC review is also required of research conducted by individuals outside of Marywood University but which is performed on the premises of Marywood University (including recruitment via email), even if the research has already been approved by the IRB at the sponsoring institution or elsewhere. Researchers outside of Marywood University must identify a full-time faculty or administrative sponsor from Marywood University.

**Mandatory Online Training for All Research Personnel**

All research personnel - principal investigators, co-investigators, research assistants, and sponsors - are required to complete two, online training courses, one in each of the following:

1. **Human Research Curriculum** (Social/Behavioral or Biomedical)
2. **Responsible Conduct of Research (RCR)** (Social/Behavioral, Humanities, or Biomedical)

Both courses must be completed via the Collaborative Institutional Training Initiative (CITI) at [www.citiprogram.org](http://www.citiprogram.org). Research personnel should not complete the member and staff course, as that is for Committee members and office staff only. Please see ORSP’s *research training policy* for information. Questions about certificates earned through institutions other than Marywood University may be directed to Dr. Laura Camlet Houser, Director of Research Compliance, at 570-340-6031 or lacamlet@marywood.edu.
Websites and Instructions

Three research review boards exist on campus, but only two involve human research. Information about the two human research boards may be found on the following websites:

1. **Exempt Review Committee (ERC):** For exempt review
   [http://www.marywood.edu/research-office/research-at-marywood/erc.html](http://www.marywood.edu/research-office/research-at-marywood/erc.html)
   Exempt studies involve no greater than minimal risk to participants. All research activities must fit into one or more of the federal exemption categories.

2. **Institutional Review Board (IRB):** For expedited or full review
   [www.marywood.edu/irb](http://www.marywood.edu/irb)
   Expedited studies involve no greater than minimal risk to participants, but all activities do not fit the federal exemption categories (e.g., audio/video taping). Full review studies usually involve greater than minimal risk to participants, unless research activities do not fit into the federal expedited categories.

Both websites contain policies and procedures, instructions, and required forms and templates. The IRB’s site also contains a “helpful tools” section, which includes a submission checklist, consent form readability tips, brief IRBNet video tutorials, and instructions on how to track changes in recent versions of Microsoft Word. Please familiarize yourself with these pages and inform your students about the availability of these tools.

Submission and Management System - IRBNet

IRBNet, an online submission and management system, is utilized by all of Marywood University’s research review boards. IRBNet may be found at [www.irbnet.org](http://www.irbnet.org). All principal investigators (PIs), co-investigators, and sponsors must create a user registration through IRBNet. The same individuals must apply an electronic signature to initial and renewal applications (Note: PIs must sign every package).

Please note that the default setting during submission is the IRB. Make sure that your students use the proper forms and select the correct board during the submission process. If they wish to apply to the ERC, they must click on a drop down arrow on the submission screen to scroll and find the ERC. Many researchers miss this part. Errors in submission may cause delays in review.

Application Requirement Reminders

Following are several important points which we ask you to share with your students.

- **Materials are not accepted outside of IRBNet.** Please do not snail mail or email any documents.

- **Be sure to utilize current forms and templates, as they are updated often.** Current versions are always available on our websites as well as in IRBNet.

- **Use only IRB or ERC templates** (i.e., consent form, assent form, recruitment permission letter, etc.). Do not create your own forms, as required information may be missed.

- **Do not submit thesis or dissertation chapters.** Instead, include narrative sections as outlined in our application forms.
• **When describing the procedures, use active vs. passive voice.** For instance, instead of saying that “participants will be given a survey,” tell them, “The researcher will give participants a survey.” Passive voice often eliminates the reference to the agent of the action. It must be clear who is engaged in research activities, and what their exact role is.

• **Thoroughly proofread and perform a computer spell check on all documents prior to submission.** This will aid in a more timely return of a board decision.

• **Uploading documents into a new project or package does not automatically send them to a board.** Researchers must click on “Submit this Package” once per package in order for it to be submitted. If a package displays a status of “Work in Progress,” it has not yet been submitted.

• **Submit to the appropriate board.** If you believe that the study qualifies for exemption and exempt forms have been completed, make sure to change the board to which you are sending in IRBNet. The default is the IRB and many people miss this step.

• **Electronically sign the submission in IRBNet.** Student projects will not be assigned for review if the sponsor’s signature is missing.

• **The application process does not end at the moment of final approval.** Following are other requirements:
  
  o **A status report is due six months** from the date of approval for all IRB studies. If the study has been completed by that time, use the status form as a closure report. The project will then be closed by the IRB.

  o If the study has not been completed within six months, the six-month status report should be submitted and marked as “Continuing.” A second and final status report will be due on or before the one-year expiration date for all IRB and ERC studies, unless renewing (see last point, below).

  o All changes, however minor, must be submitted for review and approval prior to implementation, according to policy.

  o Deviations or violations from the approved protocol, whether intentional or not, must be reported according to policy. Adverse events must also be reported according to policy.

• **If a study has not been completed by the expiration date (including data collection and analysis), it is the researcher’s responsibility to submit a continuing review application prior to the expiration.** IRBNet will send several automatic e-mail reminders to the researcher and sponsor (as long as the PI grants the sponsor “full” access when sharing the submission). **Lapses in research approval are not allowed.** If a study expires without review and approval of the IRB or ERC, all study activities must cease. We’d suggest applying for continuing review at least two months prior to the expiration date.

For questions about this guide, please contact:

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<tr>
<th>Institutional Review Board (IRB)</th>
<th>Exempt Review Committee (ERC)</th>
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<tbody>
<tr>
<td>Courene M. Loftus, MPA, CIP</td>
<td>Laura Camlet Houser, Ph.D.</td>
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<tr>
<td>Director of Human Participants Protection</td>
<td>Director of Research Compliance</td>
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<tr>
<td>Keith J. O’Neill Center for Healthy Families, Room 211</td>
<td>Keith J. O’Neill Center for Healthy Families, Room 218</td>
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<tr>
<td>Phone: (570) 961-4782, Fax: (570) 340-6068</td>
<td>Phone: (570) 340-6031, Fax: (570) 340-6068</td>
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<td>e-mail: <a href="mailto:cloftus@marywood.edu">cloftus@marywood.edu</a></td>
<td>e-mail: <a href="mailto:lacamlet@marywood.edu">lacamlet@marywood.edu</a></td>
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